IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

PRISCILLA GARCIA,

Plaintiff,

v. Civ. No. 1:21-cv-00666 MIS/JFR

BAYER ESSURE, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendants' Motion to Dismiss. ECF No. 5. Plaintiff responded, and Defendants replied and filed a Notice of Supplemental Authority. ECF Nos. 15, 16, 20. Having considered the parties' submissions, the record, and the relevant law, the Court will **GRANT IN PART** the Motion.

BACKGROUND

Plaintiff's claims arise out of injuries she allegedly suffered as a result of being implanted with the Essure permanent contraception device ("Essure device"). *See* ECF No. 1-1 at 6. The Essure device consists of a coil that is implanted into each fallopian tube, which then cause the body to form a "tissue barrier (like scar tissue)" to block fertilization. *Id.* at 5. The Food and Drug Administration ("FDA") regulates the Essure device as a Class III medical device, meaning it was required to pass a premarket approval ("PMA") process before reaching the market. ECF Nos. 5 at 2; 1-1 at 13. It did so in 2012, and this PMA has never been withdrawn. *See* ECF Nos. 5-1 at 2; 5-4 at 2. However, Defendants discontinued sales of the Essure device after December 31, 2018. *See* ECF No. 5 at 4; 5-9 at 2.

Plaintiff was implanted with the Essure device in October of 2011,[1] and had removal surgery in November of 2018, whereupon she alleges she discovered she had medical problems resulting from the device. ECF No. 1-1 at 43. Plaintiff claims that as a result of her implantation with the Essure device, she experienced weight gain, bloating, swelling, pain, bleeding, and infection, and she required additional surgery. *Id.* at 37, 43.

Plaintiff filed the Complaint in state court on February 25, 2021, alleging negligence, fraud, claims under strict products liability, and other claims pursuant to New Mexico state law related to her injuries. ECF No. 1-1 at 45–72. Defendants removed the case to this Court on July 20, 2021. ECF No. 1 at 1. Defendants now move for dismissal of Plaintiff's claims against them on the basis that Plaintiff's claims are, in their entirety, preempted by federal law, and are otherwise inadequately pled as required by Federal Rule of Civil Procedure ("Rule") 12(b)(6). ECF No. 5 at 1.

LEGAL STANDARD

In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act, thereby imposing a detailed federal oversight regime for medical devices, including various levels of oversight depending on the risk-level of a given device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the MDA, Class I devices are subject to the lowest level of oversight and Class III devices are subject to the highest. *Id.* at 316–17; *see* 21 U.S.C. § 360c(a)(1)(C)(ii). The MDA also established a rigorous premarket approval ("PMA") process for Class III devices,

[1] Whereas Plaintiff initially asserts implantation took place in 2011, ECF No. 1-1 at 43, elsewhere in the Complaint, she lists 2014 as the date of implantation, *id.* at 52, 54. She does not dispute Defendants' use of the 2011 date in their Motion. *See* ECF Nos. 5 at 5; 15.

which entails an average of 1,200 hours of time on the part of the FDA to review each application. *Riegel*, 552 U.S. at 318. The process requires that the FDA find "reasonable assurance" of a given Class III device's "safety and effectiveness," § 360e(d), but allows the FDA to nonetheless "approve devices that present great risks if they . . . offer great benefits in light of available alternatives." *Riegel*, 552 U.S. at 318. The PMA process includes review of a device's proposed labeling and may be conditional on adherence to certain performance standards or other restrictions. *Id.* at 318–19. After PMA, Class III devices are subject to reporting requirements, and the FDA has the power to withdraw approval based on new data. *Id.* at 319; § 360e(e)(1).

"Congress created no private cause of action in the MDA." *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1280 (10th Cir. 2021). Indeed, "the statute preempts *any* effort to use state law to impose a new requirement" on a device that has already been approved by the FDA. *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1344 (10th Cir. 2015). The MDA includes an express preemption provision, which states:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The MDA also states that—except for those actions brought by states themselves—all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a), (b)(1). State tort suits are not always preempted by the MDA, but to survive, state law must

impose "parallel" duties to those found in the federal regulations. *Caplinger*, 784 F.3d at 1338 (construing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

Similarly, "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 348 (2001). This is because the "FDA is empowered to investigate suspected fraud, and citizens may report wrongdoing and petition the agency to take action. . . . [T]he FDA may respond to fraud by seeking injunctive relief, and civil penalties, seizing the device, and pursuing criminal prosecutions." *Buchman*, 531 U.S. at 349 (citations omitted). "[F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court," thus encouraging applicants to submit a burdensome "deluge of information that the Administration neither wants nor needs . . . ." *Id.* at 351.

The introduction of federal law into the realm of medical devices has thus left, "by both express and implied preemption, only a narrow gap within which a plaintiff can plead a tort claim arising from the failure of a medical device." *Brooks,* 985 F.3d at 1276. That is, to survive preemption, "a plaintiff must plead conduct that (1) violates the [Federal Food, Drug, and Cosmetic Act ("FDCA")] (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA)." *Id.* at 1279. Where a plaintiff fails to thread this needle, her claims are subject to dismissal. *Id.*

As to pleading, pursuant to Rule 12(b)(6), a party may move for dismissal if the complaint fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). To survive a Rule 12(b)(6) motion, the complaint "must contain sufficient

factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This pleading standard does not impose a probability requirement, but it demands "more than a sheer possibility that a defendant has acted unlawfully." *Id*. Mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will not suffice. *Twombly*, 550 U.S. at 555. Although the court must accept the truth of all properly alleged facts and draw all reasonable inferences in the plaintiff's favor, the plaintiff still "must nudge the claim across the line from conceivable or speculative to plausible." *Brooks*, 985 F.3d at 1281.

DISCUSSION

Defendants argue that Plaintiff's six theories of liability alleged in her Complaint—design defect, failure to warn, failure to report, misrepresentation, manufacturing defect, and failure to train—are all "expressly preempted by § 360k(a), impliedly preempted by § 337(a), or both." ECF No. 5 at 7. Defendants also argue the Court should dismiss Plaintiff's claims because she failed to plead facts showing their actions actually *caused* her injuries, and because her misrepresentation claims are not pled with adequate particularity. *Id.* at 19. Defendants maintain that Plaintiff "presents no factual allegations to articulate *how* any alleged negligence, breach of warranty, or any other tortious conduct caused her injuries." *Id.* at 20. Defendants therefore argue that under the plausibility pleading standard, her claims should be dismissed. *Id.* at 21.

Plaintiff, meanwhile, maintains that her claims are not preempted as she has adequately pled that Defendants violated New Mexico laws parallel to the federal regulations. ECF No. 15 at 1. Plaintiff also contends that it was adequate that she pled

"the injuries she suffered that led to the surgical removal of the *Essure* device were the direct and proximate result of Defendants' failure to accurately disseminate information regarding the safety profile of the *Essure* product. As a result, Plaintiff was unable to make an informed decision about safer alternatives." ECF No. 15 at 10.

I. Design Defect Claims

First, Defendants argue that because Plaintiff does not allege that Defendants departed from the design that was approved by the FDA, her design defect claims are expressly preempted. ECF No. 5 at 7. Defendants also argue that by not specifically addressing her design defect claims in her response, Plaintiff has abandoned them. ECF No. 16 at 1.

Plaintiff, in turn, alleges that her strict products liability claims—presumably including her design defect claims—are not preempted, as Defendants' conduct violated state strict products liability law. ECF No. 15 at 9. In particular, she cites to N.M.R.A. Civ. U.J.I 13-1406 (2021) to argue that New Mexico law does not alter or add to the federal regulations at play. *Id.* at 8–9. Plaintiff also cites *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227–28 (9th Cir. 2013), and *Alliance Health of Santa Teresa, Inc. v. Nat'l Presto Indus.*, 2005-NMCA-053, ¶ 33, 137 N.M. 537, 546, for the proposition that New Mexico's presumption against preemption applies to the instant case. *Id.* at 2–3.

As an initial matter, the Court will address Plaintiff's claim that the presumption against preemption applies to this case. "If the statute contains an express pre-emption clause," as it does here, a court must "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993); *see also* 21 U.S.C. § 360k(a). The

presumption against implied preemption likewise does not apply to the regulation of medical devices by the FDA. *Buckman*, 531 U.S. at 347 ("[T]he relationship between a federal agency and the entity it regulates is inherently federal in character . . . ."). Plaintiff's assertion of a presumption against preemption is therefore misplaced.

Next, under New Mexico strict products liability, "a supplier in the business of putting a product on the market is liable for harm caused by an unreasonable risk of injury resulting from a condition of the product or from a manner of its use." N.M.R.A. Civ. U.J.I 13-1406. However, under federal law, "[o]nce a [medical] device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing § 360e(d)(6)(A)(i)). Where, as here, device-specific federal requirements apply to a device under the PMA process, the MDA preempts state claims "unless federal requirements impose duties that are at least as broad as those [plaintiff] seeks to vindicate through state law." C*aplinger*, 784 F.3d at 1340.

Here, as in *Caplinger*, Plaintiff fails to identify a parallel federal statute or regulation Defendants have violated, with regard to her design defect claims. *See* ECF Nos. 1-1, 15; *see also Caplinger*, 784 F.3d at 1381. Moreover, Plaintiff does not allege that Defendants deviated from the design approved by the FDA. *See* ECF Nos. 1-1, 15. These state law claims are therefore subject to preemption by the MDA, as any state law duties would be "additional" to those imposed by federal law. *See Brooks,* 985 F.3d at 1279. Additionally, as discussed more fully below, Plaintiff failed to adequately allege causation. The Court therefore finds that these claims shall be dismissed.

II. Failure-to-Warn Claims

Next, Defendants argue that Plaintiff's failure-to-warn claims are both expressly and impliedly preempted, because Plaintiff does not allege that Defendants deviated from the FDA-approved labeling. ECF No. 5 at 8. Plaintiff, meanwhile, maintains that common law failure-to-warn claims have "consistently been held not expressly or impliedly preempted by the MDA because they are parallel claims," citing cases from the Ninth, Fifth, and Seventh Circuits in support of this argument.[2] ECF No. 15 at 4. Plaintiff also contends that dismissal at the 12(b)(6) stage is improper because "adequacy of warnings is a question of fact." *Id.* at 7.

For a prescription medical device, usually, it

> isn't possible to prepare adequate directions for its safe use by laymen. And for precisely this reason, 21 C.F.R. § 801.109 generally absolves manufacturers from liability . . . so long as they label their prescription devices in a certain manner approved by the FDA. More than that, once the FDA approves a device's label as part of the premarket approval process (as it has here), the manufacturer usually may not alter the label's warnings without prior agency approval.

Caplinger, 784 F.3d at 1341 (internal citations omitted). A device maker may change its labeling without FDA approval via a "permissive mechanism, but that mechanism is not mandatory." *Brooks*, 985 F.3d at 1280 (citing 21 C.F.R. § 814.39). "[A]bsent a federal requirement that they do so, federal law expressly preempts any state-law duty requiring a manufacturer to update its labeling." *Id.* at 1280.

[2] *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).

Here, Plaintiff cites 21 C.F.R. § 803.10 and § 803.50 as parallel federal regulations that "mandate that adverse events or device malfunctions that lead to serious injury must be reported to the FDA," and argues that breach of these federal regulations is actionable under parallel state strict liability law as a failure to properly warn the FDA, doctors and patients. ECF No. 15 at 5, 9. Plaintiff contends that "[g]eneral common law negligence claims imposed by a state regarding failure to provide adequate warnings on medical device manufacturers have consistently been held not expressly or impliedly preempted by the MDA because they are parallel claims." ECF No. 15 at 4. However, the Tenth Circuit has already found that because federal regulations do not *mandate* a change in labeling in response to new reports without FDA approval, state law requirements that are more protective of consumers are definitionally not parallel, and are therefore preempted. *Brooks*, 985 F.3d at 1280.

Plaintiff further cites to NMRA Civ. UJI 13-1402 to argue that under New Mexico law, suppliers and manufacturers have a duty to warn that flows from their general duty to avoid foreseeable risk of injury. ECF No. 15 at 5. However, this duty is also *in addition* to the duty imposed by federal law, which requires reporting only to the FDA, and it is thus preempted. 21 U.S.C. § 360k(a); *see also Brooks*, 985 F.3d at 1280-81.

Plaintiff's state law claims with regard to labeling are therefore subject to preemption by the MDA, as they impose duties that are "additional" to those imposed by federal law. *Brooks*, 985 F.3d. at 1279. Moreover, Plaintiff does not allege that Defendants deviated from the warnings approved by the FDA, and, as discussed more fully below, fails to adequately allege causation. *See* ECF Nos. 1-1, 15.

Plaintiff also alleges Defendants' Motion should be denied because the alleged misrepresentations and inadequacy of warnings are issues of fact. ECF No. 15 at 7. Defendants, meanwhile, contend that the Court may take judicial notice of its exhibits, as agency records are subject to judicial notice. ECF No. 16 at 7. However, because Plaintiff's claims are preempted, the Court need not reach these other arguments. The Court therefore finds that Plaintiff's claims regarding labeling shall be dismissed. To the extent that Plaintiff's failure-to-warn claims involve reporting, the Court shall address them below.

III. Failure-to-Report Claims

Defendants argue that Plaintiff's failure-to-report claims are both expressly and impliedly preempted, as they are merely improper attempts to privately enforce the MDA with no parallel state cause of action. ECF No. 5 at 9–10. Additionally, Defendants contend these claims are inadequately pled. *Id.* at 10. Plaintiff, meanwhile, maintains that her claims are adequately pled and that her product liability claims parallel the reporting requirements enumerated in the regulations. ECF No. 15 at 10.

"[O]nly the federal government may enforce reporting requirements and investigate and respond to suspected fraud." *Brooks*, 985 F.3d at 1281. Claims based on alleged failures to properly conduct post-PMA reporting are therefore impliedly preempted as improper private "attempts to enforce the MDA." *Id.*

Here, Plaintiff argues that Defendants' alleged failures to report also constitute failures-to-warn under state tort law. ECF No. 15 at 5–7. Plaintiff argues her state tort claims are parallel to federal law, citing 21 C.F.R. §§ 803, 814 and 820 as requiring Defendants to report. *Id.* at 5. However, Plaintiff cites no state law cause of action for

failure to report adverse events to the FDA, and as discussed below, fraud-on-the-FDA claims are barred. *See* ECF Nos. 1-1, 16. Additionally, to the extent that Plaintiff argues the federal regulations parallel the state tort duty-to-warn, these duties are not truly parallel as the federal regulations invoke a duty to the FDA, not to consumers, healthcare professionals or other foreseeable users of the product. *See* NMRA Civ. UJI 13-1402. The Tenth Circuit has held that "only the federal government may enforce reporting requirements . . . ." *Brooks*, 985 F.3d at 1281. These state law claims are therefore subject to preemption by the MDA. *Id.* at 1279. To the extent that Plaintiff alleges misrepresentation via an advertisement directly to patients, the Court notes that Plaintiff does not allege she read or viewed any advertisements. *See* ECF No. 1-1 at 34. Moreover, as discussed more fully below, Plaintiff fails to adequately allege causation. *See* ECF Nos. 1-1, 15. The Court therefore finds that these claims shall be dismissed.

IV. Misrepresentation Claims

Defendants argue that Plaintiff's misrepresentation claims are expressly preempted, and that they are not pled with the particularity required by Rule 9(b). ECF No. 5 at 11, 19. Plaintiff counters that her "claims center around the FDA, her implanting physician and herself being deprived of the information that would allow them to make an informed decision regarding the implantation of this Class III device." ECF No. 15 at 11–12. Plaintiff also contends that her misrepresentation claims are not preempted by the MDA, as her claims are parallel. *Id.* at 7.

Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." In order to comply with Rule 9(b), a plaintiff must "set forth the time, place and contents of the false representation, the

identity of the party making the false statements and the consequences thereof." *Lawrence Nat'l Bank v. Edmonds (In re Edmonds)*, 924 F.2d 176, 180 (10th Cir. 1991). In general, "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman*, 531 U.S. at 348. This conflict arises because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration . . . ." *Id.* In particular, the FDA may investigate suspected fraud on its own or at a citizen's report, and may seek injunctive relief and civil penalties, seize the device, or even pursue criminal prosecutions. *Id.* at 349. Additionally, "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes [would] dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA." *Id.* at 350. For these reasons, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently" and with the FDA's goal of balancing its different policy objectives. *Id*.

To the extent that Plaintiff's claims also involve fraud upon her physician and upon herself as a patient, such claims flow factually from her allegations of fraud-on-the-FDA. Thus here, as in *Buckman*, "the fraud claims exist solely by virtue of the FDCA disclosure requirements." 531 U.S. at 353; *see also* ECF 1-1. The Court therefore finds that these claims are preempted and shall be dismissed. *Id.*

V. Manufacturing Defect Claim

Defendants allege that any claims for negligence per se are preempted, as such liability does not exist independently under state law. ECF No. 5 at 14. Defendants also argue that the manufacturing defect claims are expressly preempted and inadequately pled. *Id.* Defendants contend that by not specifically addressing her manufacturing defect

claims in her response, Plaintiff has abandoned them. ECF No. 16 at 1. Plaintiff, in turn, alleges that her strict products liability claims, presumably including her manufacturing defect claims, are not preempted as Defendants' conduct violated parallel state strict products liability law. ECF No. 15 at 9.

"Bald accusations such as 'defendant violated the law,' 'defendant failed to exercise reasonable care,' and the like will not support a claim for relief" in a claim for negligent manufacturing of a medical device. *Brooks,* 985 F.3d at 1282 (citing *Iqbal*, 556 U.S. at 679). Allegations of historical facts dealing with misconduct in conducting studies and reporting results will not suffice; a plaintiff in a manufacturing defect claim must allege facts that bear on some specific flaw or flaws in the manufacturing process relevant to a plaintiff's own medical device. *Id.* (dismissing case alleging defendant failed to properly report results or update labeling, and where whistleblowers alleged fraud).

Here, Plaintiff cites *McClellan v. I-Flow Corp*., 776 F.3d 1035, 1041 (9th Cir. 2015), for the proposition that "[s]tate law negligence per se claims can be premised on the manufacturer[']s failure to comply with the FDA's labeling requirements without being pre-empted under the MDA." ECF No. 15 at 7. However, as Defendants assert, "[a]ny negligence per se action premised on an MDA violation necessarily seeks to enforce the MDA rather than a parallel state-law duty," and is thus preempted, according to the Tenth Circuit. *Brooks*, 985 F.3d at 1280.

Additionally, here, as in *Brooks*, Plaintiff has failed to identify violations of law—state or federal—that produced actual defects in her own implant, which then caused her injuries. *See* ECF No. 1-1. Plaintiff alleges general "use of uncertified materials and non-conformity of the contract manufacturer . . . and failing to maintain proper procedure in

inventory transfer." ECF No. 1-1 at 54. Plaintiff further alleges that Defendants' manufacturing defects "caused perforation," but not that *she* suffered this injury. *Id.* at 22, 43–44.

Plaintiff alleges that "the precise scope of defects is uniquely within Defendants' possession and control." *Id.* at 29. However, to the extent that Plaintiff suffered "pain, bleeding, infection, and the need for additional surgery," namely surgery to remove the implant, she fails to connect these symptoms in a particularized way to a particular defect, even via pleading in the alternative. ECF No. 1-1 at 43, 53, 59. She does not, for example, allege that the Essure device broke, caused a puncture, or migrated into her abdominal cavity, nor does she describe how use of non-conforming material caused her particular injury. *See*, *e.g.*, *Norman v. Bayer Corp.*, 2016 WL 4007547, at *3 (D. Conn. July 26, 2016); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1095 (N.D. Cal. 2016).

Crucially, Plaintiff fails to allege that her own Essure device actually suffered from a particular manufacturing defect which caused her injury. *Id.* Unfortunately for her and for other patients, it appears the parties are in agreement that even a conforming Essure device can cause the symptoms she alleges. *See* ECF Nos. 1-1 at 46, 5 at 18–19. The Court therefore finds that these claims are inadequately pled and must be dismissed.

VI. Negligent Training Claims

Defendants argue that Plaintiff's negligent training claims are expressly and impliedly preempted, that Plaintiff fails to allege that Defendants violated FDA-approved training requirements, and that there does not exist a parallel state-law requirement to train, as failure-to-train claims in New Mexico only apply to the employer-employee relationship. ECF No. 5 at 17–19. Plaintiff contends that her claims are not preempted

because she has alleged Defendants deviated from the FDA-approved training by, among other things, using sales representatives to train physicians. ECF No. 15 at 8.

Similar to the above, Plaintiff fails to allege that her physician performed the procedure incorrectly, or how her physician's allegedly insufficient training led to an error that caused her particular injuries. *See* ECF No. 1-1. Unfortunately for her and for other patients, it appears the parties agree that even a properly-placed Essure device can cause the symptoms she alleges. *See* ECF Nos. 1-1 at 46, 5 at 18–19. The Court therefore finds that these claims are inadequately pled and must be dismissed.

VII. Timeliness of Warranty Claims

Defendants also argue that Plaintiff's claims for breach of warranty pursuant to New Mexico law are untimely as the statute of limitations is four years from the date when "delivery" occurs. ECF No. 5 at 22. Here, Defendants argue that "delivery" occurred when Plaintiff was implanted with the device, in 2011.[3] *Id.* Plaintiff does not contest the timeliness of these claims. *See generally* ECF No. 15.

Under New Mexico law, "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued." NMSA 1978 § 55-2-725(1). Further,

> [a] cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance, the cause of action

[3] Whereas Plaintiff initially asserts implantation took place in 2011, ECF No. 1-1 at 43, elsewhere in the Complaint, Plaintiff lists 2014 as the date of implantation, *id.* at 52, 54. As discussed *infra*, however, a 2014 "delivery" date would not cure the untimeliness of Plaintiff's claims.

accrues when the breach is or should have been discovered.

§ 1978 § 55-2-725(2).

Here, although Plaintiff states in her Complaint that she "did not discover that she had medical problems from the Essure[] product until on or about November 19, 2018," ECF No. 1-1 at 43, Plaintiff offers no response to Defendants' argument regarding timeliness of her claims, thus effectively abandoning them, *see* ECF No. 15.

Additionally, Plaintiff admits in the Complaint that she was given notice when the FDA convened public hearings in late 2015 regarding the problems with the Essure device. ECF No. 1-1 at 44 ("Plaintiff did not have knowledge or sufficient notice that the level of risk of injuries from Essure® was higher than she was originally led to believe, nor did she learn of any potential wrongdoing on the part of the manufacturer, until the FDA convened public Essure® hearings in late 2015."). Even, *arguendo*, applying equitable tolling and taking December 31, 2015, as the date of "delivery," Plaintiff's warranty claims, which were filed in state court on February 25, 2021, are untimely. *See* ECF No. 1-1; *see also Nowell v. Medtronic Inc*., 372 F. Supp. 3d 1166, 1241 (D.N.M. 2019), *aff'd*, *Nowell v. Medtronic, Inc*., 2021 WL 4979300 (10th Cir. Oct. 27, 2021) (finding initial surgery to implant device effected "delivery"). The Court therefore finds that these claims must be dismissed.

VIII. Pleading of Causation

Defendants also allege that Plaintiff has failed to adequately allege how Defendants' negligence may have caused her injuries. ECF No. 5 at 20. Plaintiff, meanwhile, alleges in her Complaint that "[t]he information concerning the precise scope of defects is uniquely within Defendants' possession and control." ECF No. 1-1 at

29. Plaintiff also argues that she has adequately pled causation because her injuries "were the direct and proximate result of Defendants' failure to accurately disseminate information regarding the safety profile of the Essure product. As a result, Plaintiff was unable to make an informed decision about safer alternatives." ECF No. 15 at 10 (internal citations omitted).

Plaintiff thus contends she met the pleading requirement because she suffered injury due to a lack of accurate information that led her to choose Essure. This is conclusory because it assumes the device caused her injuries. As discussed above, this is insufficient. *Norman v. Bayer Corp.*, 2016 WL 4007547, at *1 (D. Conn. July 26, 2016) (dismissing 29-page complaint where "only four short paragraphs relate to [plaintiff's] personal experience with Essure" but no "facts [] indicate that the device was improperly implanted, that it broke, [] that it had any other manufacturing defect . . . [or that] plaintiff or her doctor consulted or relied upon any particular information or warnings about the device"); *Brooks*, 985 F.3d at 1281–82 ("Plaintiffs fail to allege facts reflecting any negligence in the manufacturing of the implant or that the implant was, in fact, defective. Although the Complaint spins a wide-reaching story of noncompliance with FDA regulations and requirements, bad conduct, whistle-blower complaints, misrepresented data, and other horrors, it does little to support this highly conclusory story with specific facts.").

Dismissal of a case where a patient alleges injury from a medical device that has been discontinued, with many documented cases of unacceptable side effects, is a harsh result. It is, however, required under *Brooks*, even at the cost of disallowing

individual plaintiffs to recover for real injuries. *See*, *e.g.*, *Riegel*, 552 U.S. at 318. The Court will next proceed to consider Plaintiff's request to amend her Complaint.

IX. Request to Amend

Plaintiff requests in her Response that the Court allow her to amend her Complaint under Rule 15(a) "to make more specific factual allegations." ECF No. 15 at 11. Defendants contend the Court should deny Plaintiff's request to amend for failure to comply with the Local Rules, and for failure to explain how amendment would "cure the deficiencies in the current complaint." ECF No. 16 at 10.

Generally, "bare requests for leave to amend do not rise to the status of a motion and do not put the issue before the district court." *Brooks*, 985 F.3d at 1283; *see also Glenn v. First Nat. Bank in Grand Junction*, 868 F.2d 368, 370-71 (10th Cir. 1989). Additionally, in this District, a proposed amended complaint must normally accompany a motion to amend. D.N.M.LR-Civ. 15.1.

Here, Plaintiff has failed to either include a proposed amended complaint, or to detail what such amendment would entail. *See* ECF No. 15. Additionally, Plaintiff fails to explain why she did not initially make "more specific factual allegations," or what new information she may be able to add. *Id.* at 11. However, as the Tenth Circuit has noted, in this area of law crafting a legally sufficient complaint is so difficult that it "has been compared to the task of navigating between Scylla and Charybdis." *Caplinger*, 784 F.3d at 1340. Additionally, "[t]he court should freely give leave when justice so requires." FED. R. CIV. P. 15(a)(2). The Court will therefore grant Plaintiff's request.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss, ECF No. 5, is **GRANTED IN PART** and Plaintiff's claims are **DISMISSED WITHOUT PREJUDICE.**

IT IS FURTHER ORDERED that Plaintiff shall have until **October 28, 2022,** to file an amended Complaint. If Plaintiff fails to timely file an amended Complaint, her claims shall be dismissed with prejudice.

Margaret Strickland

MARGARET STRICKLAND
UNITED STATES DISTRICT JUDGE